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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,957	02/18/2005	Robert Petrosenko	7175-71861	1060
	7590 04/15/200 HORNBURG LLP	EXAMINER		
11 SOUTH ME	RIDIAN	BOGART, MICHAEL G		
INDIANAPOLIS, IN 46204			ART UNIT	PAPER NUMBER
			3761	
			MAIL DATE	DELIVERY MODE
			04/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
Office Action Occurrence	10/524,957	PETROSENKO ET AL.				
Office Action Summary	Examiner	Art Unit				
	MICHAEL G. BOGART	3761				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on 12 No	ovember 2007					
·= · · · · · · · · · · · · · · · · · ·	action is non-final.					
<i>,</i> —	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4)⊠ Claim(s) <u>1-7,9-16,19,23-25 and 27-29</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-7,9-16,19,23-25 and 27-29</u> is/are rejected.						
7) Claim(s) is/are objected to.	•					
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examine	•					
9) The specification is objected to by the Examiner. 10) The drawing(s) filed on 18 February 2005 is/are: a) accepted or b) objected to by the Examiner.						
	·— · ·— ·	•				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s) 1) Notice of References Cited (PTO-892)	4) 🔲 Interview Summary					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	ate				
3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 12 November 2007. 5) Information Disclosure Statement(s) (PTO/SB/08) 6) Other:						
. aps. 1.5(s)an bato 12 11070111001 2001.						

DETAILED ACTION

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-7, 12 and 23 are rejected under 35 U.S.C. § 102(b) as being anticipated by Henley *et al.* (WO 01/37922 A2; hereinafter: "Henley").

Regarding claim 1, Henley teaches a vacuum bandage system (6) capable of being used with a wound (300) having a wound surface, the vacuum bandage system (6) comprising:

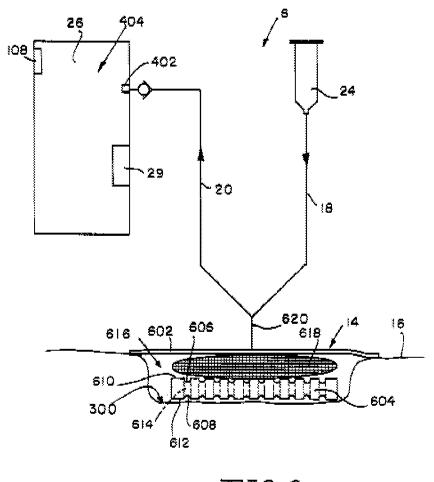
a wound dressing member (602, 618) made generally of a non-porous material (film (602) is non-porous) having a plurality of holes (interstices in porous packing (618)) and a port (602, 620) in communication with the holes and capable of being coupled to a vacuum source (110), and a wound insert (604) capable of being placed within the wound (300) between the wound surface and the wound dressing member (602, 618), the insert (604) being made of a material which is not porous or foam-like (silicone)(see fig. 9, infra, from US equivalent Risk *et al.* US 6,755,807 B2).

Henley at page 14, lines 27-32, incorporates by reference, United States application entitled VACUUM THERAPY AND CLEANSING DRESSING FOR WOUNDS, filed on November 29, 2000. Risk *et al.* US Patent 6,755,807 B2 which claims priority to the same provisional application No. 60/167,753 as Henley, indicates at col. 9, line 67 that the

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incorporated document is US application No. 09/725,352 which describes bandage insert structures (20) made of medical grade silicone (see col. 4, lines 50-67 of Lockwood *et al.* US 6,685,681 B2 which issued from the '352 application).



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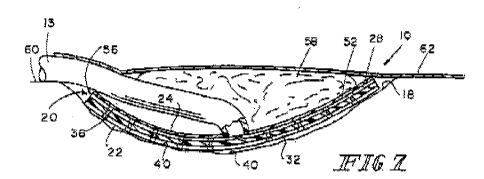
Regarding the limitation directed to how the wound dressing member is configured to engage at least a portion of the wound surface, this is a functional limitation. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function, because

apparatus claims cover what a device is, not what a device does (Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990)). Thus, if a prior art structure is capable of performing the intended use as recited in the preamble, or elsewhere in a claim, then it meets the claim. Layer (602) of Henley is capable of engaging a portion of a wound.

Regarding claim 3, Henley teaches that the wound insert (604) includes a plurality of discrete passageways (606, 608) in communication with the vacuum source (110). Regarding the insert being thin and flexible, see Lockwood *et al*.

Regarding claim 4, Henley teaches that the passageways (606, 608) are conduits through the wound insert (604).

Regarding claims 5 and 12, Henley, incorporating by reference (page 14, lines 27-32), Lockwood, teaches an insert (20, 52) that includes a top surface (53), a bottom surface (32), and side surface, and wherein the conduits (56) form holes or bores in one or more of the side surfaces, and wherein the insert (20, 52) further includes holes (36) in communication with the conduits (56) and forming holes (36) in one or more of the top and bottom surfaces (53, 32)(see Lockwood, fig. 7, infra). Further regarding claim 12, Henley teaches a thin flexible member (604) spaced away from the suction tube (620).



Regarding claims 6 and 7, Henley teaches channels (606, 608) in each of the top and bottom surfaces (610, 612) and holes (614) between the channels (606, 608).

Regarding claim 23, Henley teaches a wound insert that is capable of preventing an ulcerated portion of a wound from forming a bridge to another ulcerated portion of the wound.

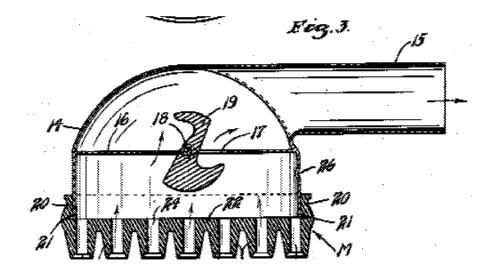
Claims 1 and 27 are rejected under 35 U.S.C. § 102(b) as being anticipated by La Mere *et al.* (US 2,338,339; hereinafter "La Mere").

Regarding claim 1, La Mere teaches a vacuum bandage system (11, 12, 13) capable of being used with a wound having a wound surface, the vacuum bandage system (11, 12, 13) comprising:

a wound dressing member (14, 16) made of a generally non-porous material and is capable of contacting a wound having a plurality of holes (17, 26) and a port (15) in communication with the holes (26) and capable of being coupled to a vacuum source (11), and a wound insert (M) capable of being placed within the wound between the wound surface and the wound dressing member (14, 16), the insert (M) being made of a material which is not porous or foam-like (rubber)(see fig. 3, infra)(col. 3, line 1).

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Regarding claim 27, La Mere teaches that the wound insert (M) comprises a plurality of rods (23) made of generally non-porous, flexible material and that are held together by webs that can be torn apart.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 2, 9-11, 13-15, 19, 24, 25, 28 and 29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Henley.

Henley does not disclose expressly the claimed sizes and shapes of the absorbent insert.

Mere changes in size or shape are not sufficient to patentably distinguish an invention over the prior art absent a showing of criticality. See *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Furthermore, Henley incorporates by reference the '352 application which teaches a dressing insert (20) that can be cut to fit the size and shape of a wound (see Lockwood *et al.* figures 4 and 6; col. 5, lines 1-10).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to provide the wound insert of Henley in any size or shape that corresponds to a wound to which it is to be applied.

Regarding claim 2, Lockwood teaches that silicone is a suitable material for a component of a bandage (col. 4, lines 40-67). Silicone is non-reactive to human skin.

Regarding claim 10, see Lockwood et al. col. 5, lines 1-10.

Regarding claim 16, Henley teaches discrete passageways (606, 608) comprising channels in the top (610) and bottom (612) surfaces.

Regarding claim 19, Henley, incorporating by reference the '352 application, teaches a dressing construction of a non-adhesive material (silicone)(see Lockwood *et al.*, col. 4, lines 50-67).

Regarding claim 25, Lockwood teaches a non-porous insert (20).

Regarding claims 28 and 29, Lockwood teaches a insert body (20, 52) that is hollow (because of passageways (36, 56, 28).

Response to Arguments

Applicant's arguments filed 12 November 2007 have been fully considered but they are not persuasive.

Applicants assert that Henley does not disclose or suggest a vacuum bandage including both a wound dressing member made of a generally non-porous material and a wound insert that is not porous or foam-like. This argument is not persuasive because Henley, as described in detail, supra, discloses a non-porous insert (604) and a wound dressing member (602, 618) that includes a generally non-porous material (602).

In response to applicant's argument that Henley does not teach a wound dressing member configured to engage at least a portion of the wound surface of the wound, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed

invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Applicants assert that Henley does not teach passageways including bores extending therethrough, Henley, incorporating by reference, Lockwood teaches such a structure (20, 52), see fig. 7, supra.

Regarding the limitations concerning the cylindrical shape of the insert, Henley incorporates by reference the '352 application which teaches a dressing insert (20) that can be cut to fit the size and shape of a wound (see Lockwood *et al.* figures 4 and 6; col. 5, lines 1-10).

Regarding the Le Mere reference, applicants assert that it does not disclose a vacuum bandage. This argument is not persuasive because the device is capable of providing suction to the skin of either healthy skin or a wound.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing

date of this final action.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the Examiner's supervisor, Tatyana Zalukaeva

may be reached at phone number (571) 272-1115. The fax phone number for the organization

where this application or proceeding is assigned is (571) 273-8300 for formal communications.

For informal communications, the direct fax to the Examiner is (571) 273-4933.

Any inquiry of a general nature or relating to the status of this application or proceeding

should be directed to the receptionist whose telephone number is (571) 272-3700.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair_direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Bogart/

Examiner, Art Unit 3761

15 February 2008

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761